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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,008	12/12/2003	Qiong Cheng	CL2028USNA	2503

23906 7590 06/30/2006

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,008

Applicant(s)

CHENG ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/22/04 & 12/20/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Election and Amendment to claims filed June 5, 2006 is acknowledged.

Applicant's election of Group I (claims 1-10, 14 & 16) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. **Claims withdrawn** :

Claims 11-13 & 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1-10, 14 & 16 are under consideration in this examination.

4. ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e), filed 11 August 2000, is acknowledged.

5. ***Enablement Rejection***

Claims 1-10, 14 & 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated β -carotene overproducing *Escherichia coli* host cell comprising the plasmid pPCB15 (cam^R) (SEQ ID NO: 43) encoding the carotenoid biosynthesis gene cluster (*crtEXYIB*) from *Pantoea stewartii*, wherein *deaD* gene is disrupted, does not reasonably provide enablement for any carotenoid overproducing microorganism comprising genes encoding a functional isoprenoid enzymatic biosynthetic pathway comprising a disrupted *deaD* gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Art Unit: 1652

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) [*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary].

The specification, however, only discloses a single example, wherein wild-type *E. coli* which is a known non-carotenogenic organism and synthesizes only the farnesyl pyrophosphate precursor for carotenoids is transformed with plasmid pPCB15 (cam^R) (SEQ ID NO: 43) encoding the isoprenoid enzymatic pathway biosynthesis gene cluster (*crtEXYIB*) from *Pantoea stewartii*, wherein *deaD* gene is disrupted. Beyond the single construct (see Example 3 & Figure 1) there is no guidance provided wherein any microorganism can be transformed with the plasmid construct or any of the isoprenoid enzymatic pathway genes from any source resulting in overproduction of the carotenoids. Thus the claims are directed to specifically encompass enormous numbers of embodiments expected to be inoperative. Since it is not routine in the art to engage in *de novo* experimentation to transform any microorganism by transforming the isoprenoid enzymatic pathway biosynthesis genes from any source and leading to over producing of any carotenoid where the expectation "of success is

Art Unit: 1652

unpredictable", the skilled artisan would require additional guidance in order to make and use such microorganisms in a manner reasonably commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

6. **35 U.S.C. § 112, first paragraph (Written Description)**

Claims 1-10, 14 & 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-10, 14 & 16 are drawn to any carotenoid overproducing microorganism comprising genes encoding a functional isoprenoid enzymatic biosynthetic pathway comprising a disrupted *deaD* gene, the claimed genus.

The specification, however, only provides a single species in an isolated β -carotene overproducing *Escherichia coli* host cell comprising the plasmid pPCB15 (*cam*^R) (SEQ ID NO: 43) encoding the carotenoid biosynthesis gene cluster (*crtEXYIB*) from *Pantoea stewartii*. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species to other species where such sequences or constructs are similar in order to establish a relationship among species to be representative of the claimed genus.

The specification also fails to describe additional representative species of these isoprenoid biosynthetic pathway genes by any identifying structural characteristics other than the properties or activity recited in claims, for which no predictability of structure is apparent. Given this lack of

Art Unit: 1652

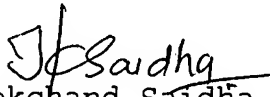
additional representative species, and in a manner to be representative of the claimed genus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Therefore, the written description requirement is not satisfied.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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